

REMARKS

This Amendment is being filed in response to the Office Action mailed from the U.S. Patent and Trademark Office on March 13, 2003, in which claims 11-32 were rejected and claims 33-40 were withdrawn from consideration. With this Amendment, claim 22 is canceled and claims 11, 15, 19 and 23 are amended. As such, Applicants respectfully request reconsideration and allowance of pending claims 11-32.

The Office Action objected to claim 15 under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Office Action rejected claims 19 and 23 under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action rejected claims 11-20, 22, 23, 26, 27, 30, 31, and 32 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,103,518 to Leighton ("the Leighton '518 patent"). Also, the Office Action rejected claims 21, 24, 25, 28 and 29 under 35 U.S.C. § 103(a) as being unpatentable over the Leighton '518 patent in view of various combinations of U.S. Patent No. 5,515,861 to Smith, U.S. Patent No. 3,689,595 to Gwinn and U.S. Patent No. 6,036,698 to Fawzi et al.

The Office Action stated on page 3 that during a telephone conversation with Paula Evans on February 28, 2003, a provisional election was made with preservation of right to traverse to prosecute the invention of Group I, claims 11-32. Applicants hereby confirm election of **Group I (Claims 11-32)** for prosecution on the merits, with traverse.

The Office Action objected to claim 15 under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. With this Amendment, claim 15 has been amended to depend from claim 11 and not claim 13 to overcome this objection.

The Office Action rejected claims 19 and 23 under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With this Amendment, claims 19 has been amended to depend from

claim 18 instead of claim 13, and claim 23 has been amended to depend from claim 11 instead of claim 17. Thus, this rejection is overcome.


The Office Action rejected claims 11-20, 22, 23, 26, 27, 30, 31, and 32 under 35 U.S.C. § 102(e) as being anticipated by the Leighton '518 patent.

The Office Action stated on page 6:

The reference of Leighton discloses a stylet (32) which includes a push surface (See Figure 2e) and a connecting end for connecting to a stylet body (34). The stylet body (34) includes a lumen for receiving the connecting end of the stylet (See Figure 2a). With respect to the material of the stylet pushing surface, the reference discloses that the stylet can be made of surgical steel or Teflon coated plastic (See column 8, line 35-46). These are materials recited in the instant specification which meet the required function recited in claim 11 of "maintain a temperature from -20° to 4° C during the process". With respect to the claimed prevention of rotation, as shown in Figure 2a, the stylet (32) is inherently mounted within body (34) without lateral or rotational movement, if not, the stylet (32) would not be capable of forcing the tissue sample out of the coring needle by pushing.

To anticipate a claim, the reference must teach every element of the claim. M.P.E.P. 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); M.P.E.P. 2131. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989); M.P.E.P. 2131.

With this Amendment, Applicants have amended independent claim 11 to claim a stylet having a **stylet support tube extending from the stylet body that surrounds a portion of the stylet needle**. The Leighton '518 patent does NOT disclose or suggest a stylet that includes a **stylet support tube extending from the stylet body that surrounds a portion of the stylet needle**. Instead, the Leighton '518 patent discloses a stylet with a punch tube and does NOT have a stylet support tube extending from the stylet body that surrounds a portion of the stylet needle.



Amended independent claim 11 recites a stylet needle having a **stylet support tube extending from the stylet body that surrounds a portion of the stylet needle**. With this Amendment, no new matter is added. Support for this Amendment can be found in at least FIG. 1A and FIG. 2B and the following passages from Applicants' specification:

In a preferred embodiment, **the stylet needle 3 is protected from breakage by being supported and is at least partially enclosed within a stylet tube 4** (shown in Figure 2B) for fitting the stylet needle 3 within the stylet body 2 and preventing rotation of the needle 3 within the tube 4. In one embodiment of the invention, the stylet tube 4 comprises stainless steel, such as 316th stainless 21 and 23 gauge stainless steel. **The support function of the stylet tube 4 is especially desirable when frozen tissues are being arrayed**, given a generally higher pushing force needed to push frozen embedding matrix and/or frozen tissue out of the coring needle of the arrayer which causes the needles of the prior art to break frequently which necessitates stopping the arraying process to replace the stylet. (Applicants' Specification; P. 6, Line 25 through P. 7, Line 4, Emphasis Added).

In a preferred embodiment, the stylet needle is **at least partially enclosed within a stylet tube**. (Applicants' Specification; P. 2, Lines 23-24, Emphasis Added).

In one embodiment of the invention, the stylet needle 3, which is capped at one end with the cap 8, **fits into the stylet tube 4**, bringing the stylet base 6 and connecting portion 7 into proximity with the stylet cap 8 (see Figure 1A). (Applicants' Specification; P. 8, Lines 21-23, Emphasis Added).

Applicants have amended independent claim 11 to claim a stylet having a stylet support tube extending from the stylet body that surrounds a portion of the stylet needle.

The Leighton '518 patent discloses an instrument for constructing tissue arrays. The Leighton device comprises a stylet surrounded by a punch tube, with the punch tube being used to handle the tissue. The Leighton '518 patent discloses:

On one side of the stylet there is provided an inclined recipient punch drive comprising a reciprocating ram that carries a **tubular recipient punch** at its distal end. On the other side of the stylet there is provided an inclined donor punch drive comprising a reciprocating ram that carries a **tubular donor punch** at its distal end. (Leighton '518 patent; Col. 3, Lines 52-58, Emphasis Added).

Each punch is provided with its own stylet for clearing material within the punch. **Each stylet has an outer diameter approximating that of the inner diameter of the punch with which it is associated**, but is slightly smaller than the inner

B


diameter of the punch so as to be slidably guided within the punch. (Leighton '518 patent; Col. 8, Lines 35-38, Emphasis Added).

The present invention solves this problem in a simple manner and uses the stylet 32 which is already present within the punch tube 31 as the probe to sense the surface of the block. The stylet is manufactured to protrude a fixed and known distance from the bottom of the **punch tube** when the punch tube is empty of donor or recipient material and the stylet has extended all the way to the bottom of the punch. Thus, as the punch is brought down to the block, the stylet will be the first element to touch the block as shown in FIG. 2b. The stylet is free-floating at this stage (i.e., stepper motor if employed is inactivated) in the cycle, thus it will not penetrate into the block 30 as the punch tube 31 is brought further down. The stylet tip will remain resting on the surface of the block but **the punch will continue to move downward relative to the block and relative to the stylet**. This is the same as saying that the stylet will move up with respect to the punch tube. This relative motion can be detected in a number of simple, precise and robust ways, giving rise to a signal which is routed to a computer or other control means (not shown). The control means can then record the signal corresponding to the current position of the punch, and thus records the position of the surface of the block. (Leighton '518 patent; Col. 11, Lines 13-35, Emphasis Added).

The Leighton '518 patent does NOT disclose a stylet having a **stylet support tube extending from the stylet body that surrounds a portion of the stylet needle**. Thus, Leighton does NOT anticipate or suggest the Applicants' claimed invention. As such, Applicants respectfully request reconsideration and allowance of pending claims 11-32.

The Office Action rejected claims 21, 24, 25, 28 and 29 under 35 U.S.C. § 103(a) as being unpatentable over Leighton '518 patent in view of various combinations of U.S. Patent No. 5,515,861 to Smith, U.S. Patent No. 3,689,595 to Gwinn and U.S. Patent No. 6,036,698 to Fawzi et al.

"Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." M.P.E.P. 2143.01. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 U.S.P.Q.2d 1313, 1317 (Fed.



Cir. 2000). See also *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992); M.P.E.P. 2143.01.

As discussed above, Applicants have amended independent claim 11 to further distinguish the Applicants' claimed invention over the cited prior art and overcome the Office Action's rejections. Leighton does NOT disclose a stylet having a stylet support tube extending from the stylet body that surrounds a portion of the stylet needle. The additional references cited under the various § 103 rejections do not cure or offer a suggestion on how to overcome the deficiencies of Leighton. As such, Applicants respectfully request reconsideration and allowance of pending claims 11-32.

In summary, the cited prior art references, alone or in combination, do not anticipate, suggest, or make obvious Applicants' claimed invention in pending claims 11-32 and the rejections in the Office Action should accordingly be withdrawn. Reconsideration and allowance of pending claims 11-32 is respectfully requested.

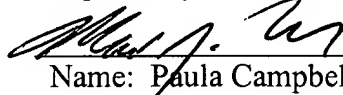
With this Amendment, Applicants have made an earnest effort to respond to all issues raised in the Office Action of March 13, 2003, and to place all claims presented in condition for allowance. No amendment made was for the purpose of narrowing the scope of any claim, unless Applicants have argued herein that such amendment was made to distinguish over a particular reference or combination of references.



Applicants submit that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

Date: August 13, 2003

Respectfully submitted,



Name: Paula Campbell Evans
Registration No.: 32,503
Customer No.: 29932
Palmer & Dodge LLP
111 Huntington Avenue
Boston, MA 02199-7613
Tel: 617-239-0100

*Mark J. Fitzgerald
Reg. No. 45,928 for
Paula Campbell Evans*

